United States District Court

EASTERN DISTRICT OF TEXAS
SHERMAN DIVISION

ORTHOACCEL TECHNOLOGIES, INC.	§	
	§	
v.	§	Civil Action No. 4:16-cv-00350-ALM
	§	Judge Mazzant
PROPEL ORTHODONTICS, LLC	§	
	§	

MEMORANDUM OPINION AND ORDER

Pending before the Court is Propel Orthodontics, LLC's Motion for Partial Summary Judgment Regarding FDA Compliance (Dkt. #264). The Court, having considered the relevant pleadings, finds Propel Orthodontics, LLC's motion is denied.

BACKGROUND

Plaintiff, OrthoAccel Technologies, Inc. ("OrthoAccel"), is a medical device company that manufactures dental appliances. In 2008, OrthoAccel developed a prototype hands-free dental device that uses gentle vibrations to accelerate tooth movement when used with orthodontic treatment. This prototype would eventually become the AcceleDent device, which has two main functional components: (1) a "Mouthpiece" and (2) an "Activator." The Activator is a small extraoral component that generates a vibrational force of 0.25N at 30 Hz. The Activator connects directly to the Mouthpiece, which the patient lightly bites down on for 20 minutes daily to accelerate tooth movement during orthodontic treatment.

On November 5, 2011, the Food and Drug Administration ("FDA") granted 510(k) clearance for AcceleDent as "an orthodontic accessory intended for use during orthodontic treatment. It is used in conjunction with orthodontic appliances such as braces and helps facilitate minor anterior tooth movement." A 510(k) is a premarketing submission made to the FDA to demonstrate that the device to be marketed is as safe and effective as a legally marketed device (a

"predicate device") that is not subject to premarket approval. 510(k) clearance is required for Class II devices, but Class I devices are 510(k) exempt. Thus, a Class I device is not "cleared"; rather, a Class I device is "exempt." Class I devices are deemed to be low risk and are therefore subject to the least regulatory controls. For example, dental floss is classified as a Class I device. Class II devices are higher risk devices than Class I and require greater regulatory controls to provide reasonable assurance of the device's safety and effectiveness. Class II devices are either "exempt" or "cleared." Dental implants and braces are examples of Class II devices. Class III devices are high-risk medical devices—such as a pacemaker—that require a more rigorous premarket review than the 510(k) pathway. Class III devices are "approved" by the FDA.

In 2012, OrthoAccel launched its Class II AcceleDent device in the United States to be used in conjunction with orthodontic treatment. In 2013, OrthoAccel launched the AcceleDent Aura ("Aura"), the second generation of AcceleDent, which initially was cleared to be used with braces only.

Defendant Propel Orthodontics, LLC ("Propel") is also a medical device company that manufactures dental appliances. In January 2016, Propel began marketing a vibratory Class I device designed to help seat clear aligners. Orthodontic patients wear a series of these removable aligners, marketed under names such as Invisalign and ClearCorrect, to gradually straighten their teeth. In March 2016, Propel released the VPro5, which operates at 120 Hz and requires five minutes of daily use to properly seat (i.e., fit better on the teeth) clear aligners. The VPro5 costs significantly less than the OrthoAccel Aura. On July 8, 2016, OrthoAccel's product—the Aura—was cleared for use with clear aligners.

Propel primarily markets the VPro5 nationwide through its sales force in a consultative setting. Propel sales representatives originally promoted the VPro5 by telling orthodontists that

the device offers several clinical benefits ("5 Clinical Benefits"). These 5 Clinical Benefits include: (1) more efficient aligner seating, (2) relieves orthodontic pain, (3) accelerates tooth movement, (4) fast tracks retention, and (5) stimulates bone growth and remodeling. Propel's sales force originally marketed the VPro5 as a quicker, cheaper alternative to the AcceleDent device.

In May 2016, OrthoAccel sued Propel, claiming Propel falsely advertised the VPro5's 5 Clinical Benefits in violation of the Lanham Act. On October 26, 2016, the Court entered a preliminary injunction enjoining Propel from advertising the 5 Clinical Benefits (Dkt. #148). On January 13, 2017, Propel filed this Motion for Partial Summary Judgment Regarding FDA Compliance (Dkt. #264). On January 27, 2017, OrthoAccel filed a response (Dkt. #276). On February 6, 2017, Propel filed a reply (Dkt. #283). On February 14, 2017, OrthoAccel filed a sur-reply (Dkt. #291).

LEGAL STANDARD

The purpose of summary judgment is to isolate and dispose of factually unsupported claims or defenses. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323–24 (1986). Summary judgment is proper under Rule 56(a) of the Federal Rules of Civil Procedure "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). A dispute about a material fact is genuine when "the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby Inc.*, 477 U.S. 242, 248 (1986). Substantive law identifies which facts are material. *Id.* The trial court "must resolve all reasonable doubts in favor of the party opposing the motion for summary judgment." *Casey Enters., Inc. v. Am. Hardware Mut. Ins. Co.*, 655 F.2d 598, 602 (5th Cir. 1981).

The party seeking summary judgment bears the initial burden of informing the court of its motion and identifying "depositions, documents, electronically stored information, affidavits or

declarations, stipulations (including those made for purposes of the motion only), admissions, interrogatory answers, or other materials" that demonstrate the absence of a genuine issue of material fact. Fed. R. Civ. P. 56(c)(1)(A); *Celotex*, 477 U.S. at 323. If the movant bears the burden of proof on a claim or defense for which it is moving for summary judgment, it must come forward with evidence that establishes "beyond peradventure *all* of the essential elements of the claim or defense." *Fontenot v. Upjohn Co.*, 780 F.2d 1190, 1194 (5th Cir. 1986). Where the nonmovant bears the burden of proof, the movant may discharge the burden by showing that there is an absence of evidence to support the nonmovant's case. *Celotex*, 477 U.S. at 325; *Byers v. Dall. Morning News, Inc.*, 209 F.3d 419, 424 (5th Cir. 2000). Once the movant has carried its burden, the nonmovant must "respond to the motion for summary judgment by setting forth particular facts indicating there is a genuine issue for trial." *Byers*, 209 F.3d at 424 (citing *Anderson*, 477 U.S. at 248–49). A nonmovant must present affirmative evidence to defeat a properly supported motion for summary judgment. *Anderson*, 477 U.S. at 257. Mere denials of material facts, unsworn allegations, or arguments and assertions in briefs or legal memoranda will not suffice to carry this burden. Rather, the Court requires '"significant probative evidence'" from the nonmovant to dismiss a request for summary judgment. *In re Mun. Bond Reporting Antitrust Litig.*, 672 F.2d 436, 440 (5th Cir. 1982) (quoting *Ferguson v. Nat'l Broad. Co.*, 584 F.2d 111, 114 (5th Cir. 1978)). The Court must consider all of the evidence but "refrain from making any credibility determinations or weighing the evidence." *Turner v. Baylor Richardson Med. Ctr.*, 476 F.3d 337, 343 (5th Cir. 2007).

ANALYSIS

Propel asks the Court to grant partial summary judgment in favor of Propel against OrthoAccel's claims that Propel falsely advertised the VPro5 as FDA registered, cleared, or

approved between January 2016 and May 19, 2016. Propel claims that it complied with all FDA regulations by listing the VPro5 as a 510(k) exempt Class I medical device. Further, Propel claims there is no evidence that Propel promoted the VPro5 as FDA-registered, FDA-cleared, or FDA-approved. OrthoAccel contends it never alleged Propel violated FDA regulations; rather, Propel falsely advertised the VPro5 as a FDA-registered, FDA-cleared, or FDA-approved device despite the undisputed fact that it is not.

Essentially, Propel argues that because the VPro5 was FDA-complaint, the Court should grant summary judgment on the FDA-related false advertising claims. But FDA compliance is not dispositive here. Even if Propel correctly listed the VPro5, Propel could be liable for falsely advertising that the device was registered, cleared, or approved by the FDA. The parties agree that the VPro5 is not FDA-registered, FDA-cleared, or FDA-approved. Thus, the Court must determine whether there is a genuine issue of fact regarding whether Propel advertised the VPro5 as a registered, cleared, or approved device.

In the Fifth Circuit, the elements of a false advertising claim under the Lanham Act are: (1) the defendant made a false statement of fact about its product in a commercial advertisement; (2) the statement actually deceived or had a tendency to deceive a substantial segment of its audience; (3) the deception was material or likely to influence the purchasing decision; (4) the defendant caused the false statement to enter interstate commerce; and (5) the plaintiff has been or is likely to be injured as a result. *Logan v. Burgers Ozark Country Cured Hams, Inc.*, 263 F.3d 447, 462 (5th Cir. 2001); 15 U.S.C. § 1125. Propel claims OrthoAccel has not met its burden in showing a genuine issue of material fact exists for these elements.

OrthoAccel claims it has sufficiently evidenced that Propel made a false statement of fact about its product in a commercial advertisement. The Court agrees. Propel trained approximately

seventeen salespersons at its March 2016 launch presentation to tell customers that the VPro5 is FDA-approved and FDA-registered. Propel's CEO Bryce Way testified that the launch presentation was designed to "stimulate and educate the sales force" so the representatives could sell the VPro5 (Dkt. 113, Exhibit A). At this meeting, Propel representatives presented, "Vibration Objections and Answers," a document that instructed its sales force to respond to specific customer questions with rehearsed answers (Dkt. #179). One of the questions asks, "Is the device FDA approved?" Propel representatives trained its sales force to respond with, "Yes, we are registered as a class 1 medical device."[1] The sales force subsequently advertised the VPro5 across the country to orthodontists and dentists in consultative presentations, amounting to "hundreds of thousands of communications . . . with doctors or staff." (Dkt. #11 at 9). OrthoAccel has shown that customers were told "the major difference between the two products is the frequency . . . it moves the teeth about 50% faster and is half the cost of AcceleDent," and based on these communications, customers were led to believe that "the VPro5 was claimed to have benefits similar to or exceeding those of AcceleDent," a Class II medical device (Dkt. #215 at 13). OrthoAccel has shown that there is genuine issue of material fact regarding whether Propel advertised the VPro5 as approved or cleared by the FDA. Because any such statements would be literally false, the Court need not determine whether the marketing claims were material or deceived its audience. *See Pizza Hut, Inc. v. Papa John's Intern., Inc.*, 227 F.3d 489, 497 (5th Cir. 2000) ("With respect to materiality, when the statements of fact at issue are shown to be literally false, the plaintiff need not introduce evidence on the issue of the impact the statements had on customers."); *S&H Industries, Inc. v.*

[1] Further, Propel trained its sales force to try to embarrass customers who asked whether the VPro5 was FDA-approved or FDA-cleared by practicing the "flinching technique" and responding with "are you seriously asking if we are FDA approved/cleared? Of course we are in compliance with the FDA" (Dkt. #276, Exhibit B). This instruction from Propel's Vice President of Sales occurred after the relevant period, but the Court finds it probative to its determination that there is a genuine issue of material fact regarding whether Propel falsely advertised the VPro5 as FDA cleared or approved.

Selander, 932 F. Supp. 2d 754 (N.D. Tex. 2013) (citing *Logan*, 263 F.3d at 462; *Pizza Hut*, 227 F.3d at 497) ("If the statements at issue are shown to be literally false, a court must assume that the statements actually misled consumers, without requiring any evidence of their impact on consumers.").

OrthoAccel has shown a genuine issue of material fact regarding the final two elements of a Lanham Act claim. Propel admits that it advertised the VPro5 to doctors across the country in a consultative setting (Dkt. #11). OrthoAccel has met its burden in showing the FDA-related false advertising claims were sufficiently disseminated in interstate commerce. *See Seven-Up*, 86 F.3d 1379, 1384 (5th Cir. 1996) (finding that promotion to those specifically intended to buy the defendants' product was sufficient dissemination). OrthoAccel has also evidenced the final element, likelihood of injury, by showing that OrthoAccel has lost sales and market share from Propel's alleged false advertising. During the 39-month period before Propel launched the VPro5 and began their alleged false advertising, OrthoAccel's monthly net revenues increased on a year-over-year basis in 38 of 39 months (Dkt. #207). OrthoAccel's annual operating plan and actual revenues varied by 7% in 2014 and 2% in 2016. OrthoAccel experienced a sharp decline in sales following the launch of the VPro5, resulting in a variance of 57% from April to July 2016 (Dkt. #95, Exhibit 1). OrthoAccel has shown a genuine issue of material fact exists for its FDA-related Lanham Act claim.

Propel raises a new argument in its response—that Propel is entitled to summary judgment on OrthoAccel's FDA-related Lanham Act claim because OrthoAccel did not identify any facts in its August 31, 2016 interrogatory responses. The interrogatory requested "all facts and circumstances supporting or otherwise relating to OrthoAccel's contention that Propel has violated the Lanham Act" (Dkt. #283, Exhibit E). Propel quotes a bankruptcy court case to support its

proposition that it is entitled to a "no-evidence" summary judgment. *See In re Hydro-Action, Inc.*, 341 B.R. 186, 194 (Bankr. E.D. Tex. 2006) ("[I]f the Drewery Defendants had filed interrogatories with the Trustee requesting information on the specific instances of wrongdoing, and if the Trustee had failed to respond sufficiently, the entry of a 'no-evidence' summary judgment would be appropriate."). But the court did not find an insufficient interrogatory response independently sufficient to grant summary judgment. Further, Propel omitted the word "Perhaps" from the beginning of its quoted excerpt. *See id.* ("*Perhaps* if the Drewery Defendants had filed interrogatories . . . .") (emphasis added). Discovery in this case is ongoing and Federal Rule of Civil Procedure 26(e)(1)(A) provides a mechanism for OrthoAccel to supplement its interrogatories "if the party learns that in some material respect the disclosure or response is incomplete or incorrect."

CONCLUSION

After a careful review of the record and the arguments presented, the Court is not convinced that there are no material issues of fact entitling Propel to judgment as a matter of law on OrthoAccel's FDA-related false advertising claim. This claim should proceed to trial.

It is therefore **ORDERED** that Propel Orthodontics, LLC's Motion for Partial Summary Judgment Regarding FDA Compliance (Dkt. #264) is hereby **DENIED**.

SIGNED this 26th day of April, 2017.

AMOS L. MAZZANT
UNITED STATES DISTRICT JUDGE